Attorney's Docket No.: 01194-458001 / 03-282

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: DiMatteo et al. Art Unit: 1618

Serial No.: 10/615,276 Examiner: Nabila G. Ebrahim

Filed: July 8, 2003 Conf. No.: 8211

Title : AGENT DELIVERY PARTICLE

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Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## REPLY TO ACTION OF FEBRUARY 6, 2007

In reply to the Office Action of February 6, 2007, Applicants submit the following remarks. Claims 1, 3-15, 17-27, 29-33, 35-37 are presented for examination.

The Examiner rejected claims 8 and 10 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement, because the claims allegedly recite an antibody without any deposit information. During a Telephone Interview with the Examiner on February 22, 2007, Applicants explained that the antibodies covered by claims 8 and 10 are publicly known and are, for example, commercially available. Following a consultation with the Examiner's SPE, the Examiner withdrew the rejection of claims 8 and 10 under 35 U.S.C. § 112.

The Examiner rejected claim 25 under 35 U.S.C. § 112, second paragraph, as being indefinite. However, contrary to the Examiner's assertion, claim 25 does not relate to the subject matter covered by claim 21. Instead, claim 25 depends directly from claim 15 and covers methods of delivering to a subject a composition including a substantially spherical polymer particle, the methods include puncturing the skin and injecting the composition. Therefore, Applicants request that the rejection of this claim be reconsidered and withdrawn.

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The Examiner rejected claims 1, 3-15, 17-24, 26-27, 29-33, and 35-37 under 35 U.S.C. 103(a) as being unpatentable over Br. J. Surg., Vol. 70 (1983), pages 596-598 ("Chamberlain") or PCT Application WO 02/34300 ("Gray") in view of U.S. Patent No. 6,015,542 ("Kaminski"); AJNR 1993, 14: 571-582 ("Ajay"); U.S. Patent No. 4,970,062 ("Atcher"); and/or AAPS PharmSciTech, 2001, 2(1) Technical Note 2 ("Jo"). Claims 1, 3-15, 17-24, 26-27, 29-33, and 35-37 cover particles including a first region including pores having a first predominant pore size and a second region surrounding the first region and including pores having a second predominant pore size, the first predominant pore size is larger than the second predominant pore size. The Examiner concedes that neither Chamberlain nor Gray disclose particles having the distribution of pores as required by claims 1, 3-15, 17-24, 26-27, 29-33, and 35-37. (Office Action, page 9). And to the extent that Jo discloses porous microspheres, Jo discloses that his polymer microspheres have either high or low pore densities. (See, e.g., Jo, page 2, col. 1, lines 17-41). Jo does not explicitly disclose the pore size distribution of his particles, and certaininly does not disclose the pore size distribution required by claims 1, 3-15, 17-24, 26-27, 29-33, and 35-37, nor does Jo inherently disclose such particles. Further, neither Kaminski, Ajay, Atcher, nor Jo, alone or in combination, cure Chamberlain's or Gray's infirmities, at least because neither Karminski, Ajay, Atcher, nor Jo disclose or suggest particles including a first region including pores having a first predominant pore size and a second region surrounding the first region and including pores having a second predominant pore size, the first predominant pore size is larger than the second predominant pore size.

None of Chamberlain, Gray, Kaminski, Ajay, Atcher, or Jo, alone or in combination, discloses or suggests the particles covered by claims 1, 3-15, 17-24, 26-27, 29-33, and 35-37. There is no suggestion to combine these references to provide such particles, and, even if the references were combined, the result still would not be the particles covered by claims 1, 3-15, 17-24, 26-27, 29-33, and 35-37. Therefore, Applicants request that the rejection of these claims be reconsidered and withdrawn.

For at least the reasons above, Applicants believe the claims are in condition for allowance, which action is requested.

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Respectfully submitted,

Date: April 3, 2007

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